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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,792	01/28/2004	Daniel C. Sigg	P0011213.00	3983

27581 7590 01/28/2008

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,792	SIGG ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,24-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,24-26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 November 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on November 5, 2007. Claims 23 and 27 have been cancelled. Claims 1-22, 24-26 and 28-30 are pending.

Oath/Declaration

2. In view of the Response filed November 5, 2007, the objections made against the Oath/Declaration in the Office Action of July 3, 2007 have been withdrawn.

Drawings

3. Acknowledgement is made of the replacement drawings received on November 5, 2005. The drawings are objected to under 37 CFR 1.83(a) because they must show every feature of the invention specified in the claims. As to Claim 26, the lead as defined by Claim 22 and further comprising "a porous layer overlaying the layer of catalytic agent" must be shown or the feature(s) canceled from the claim(s). Although, the drawings show a lead including the limitations of Claim 22 comprising a catalytic layer 35 overlaying a polymeric layer 50 (see, for example, Applicant's Figs. 5A-5B), the embodiment of the lead defined by Clam 26 is not shown and/or illustrated. None of Applicant's drawings depict a porous layer overlaying a layer of a catalytic agent. No new matter should be entered.

4. With regard to Claim 29, a plug held within a porous sidewall of a porous electrode "and including a layer of catalytic agent ... on an outer surface of the plug" must be shown or the feature(s) canceled from the claim(s). Applicant's Fig. 8B illustrates a plug 89 held within a porous sidewall of

a porous electrode 832 and a catalytic layer 36 overlaying the sidewall of the porous electrode 832. Specifically, the catalytic layer 36 is shown as being on an outer surface of the electrode 832, not the plug 89. No new matter should be entered.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because Applicant's recent Amendment changed "Fig. 5" to read, "Fig. 5A", however, corresponding changes were not made through the disclosure (see paragraphs 29-30 and 33, for example). Appropriate correction is required.

Claim Objections

7. In view of the Response filed November 5, 2007, the objections made against the claims in the Office Action of July 3, 2007 have been withdrawn.

8. Claims 8, 9, 13 and 22 are objected to because of the following informalities: there appears to be an inadvertent error at the last line of the claim. As to Claims 8, 9 and 13, the Examiner suggests changing instances of "device body" to read "elongate body" instead in order to remain consistent with the recited terminology. At the last line of Claim 22, the Examiner suggests changing "polymeric layer in an area" to read "lead body in an area" instead since Claim 22 does not previously recite that the lead include or comprise "a polymeric layer". Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. In view of the Response filed November 5, 2007, the 35 U.S.C. 112, first paragraph rejections applied against the claims in the Office Action of July 3, 2007 have been withdrawn.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the

contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. ***Claims 1-4, 6-8, 10-12, 14, 16-22, 25, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holleman et al. (U.S. 5,115,818) (herein Holleman) in view of Batchelor et al. (U.S. 2002/011559) (herein Batchelor).*** As to Claims 1-4, 6, 16-22, 28 and 30, Holleman expressly discloses an implantable endocardial/epicardial therapy delivery and/or diagnostic lead (see Holleman Abstract, Figs. 1 and 4, column 1, lines 1-58, lines 34-49 and column 4, lines 5-28). Holleman specifies that the lead may include the distal assembly of the body implantable lead taught by Stokes (U.S. 4,506,680) (herein Stokes '680), incorporated by reference. The lead of Stokes includes a distal tip electrode 22 and tines, read as fixation elements 26. Tine fixation elements 26 are inherently capable of securing the lead to an implant site (see Stokes '680 Abstract, Figs. 1-3 and column 2, lines 28-65). Holleman further discloses that the lead comprises an elongated coiled conductor extending within the lead to the proximal end of the lead (see Holleman column 2, lines 33-40 and column 4, lines 5-11).

13. The lead comprises an elongate body, which carries the elongated coiled conductor and Holleman specifies that a polyurethane polymeric layer 12 forms the elongate body. An electrode 10 is positioned along an outer surface of the polymeric layer 12 forming the elongate body. Electrode 10 comprises multiple coil turns overlaying layer 12 and electrode 10 is coupled to the coiled conductor extending within the body formed by layer 12 via sleeve 20. Holleman further discloses a layer 14, present on outer surface of the electrode 10 and the outer surface of the polymeric layer 12 only along those portions of polymeric layer 12 which the electrode 10 is positioned, the layer 14

being exposed between the coil turns of the electrode 10 in order to stabilize the electrode 10 on the elongate body formed by polymeric layer 12 and to prevent fibrotic in-growth around the individual coil turns of the electrode 10 (see Holleman Abstract, Figs. 1 and 4, column 1, lines 25-31 and column 2, lines 4-45). Holleman discloses the claimed invention, as previously discussed, except that it is not specified that layer 14 is one of a of a catalytic agent, having nitrite reductase and/or nitrate reductase, or nitrosothiol reductase activity such that the catalytic agent converts nitrite/nitrate or nitrosothiols found in blood to nitric oxide.

14. Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that by providing biocatalysts or biomimetic catalysts on blood contacting surfaces of implantable biomedical devices, platelet activation and/or adhesion onto these surfaces is prevented, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23).

15. Batchelor further teaches that a material in accordance with the antithrombogenic desirability may be made or manufactured in one of a plurality of embodiments. In a first embodiment, the material includes a polymeric layer having a layer of a catalytic agent where the double layer material is attached to the surface of a metal or polymeric implantable medical device. In a second embodiment, a polymeric implantable medical device itself supplies the polymeric layer for the

material and only a catalytic agent is attached to the surface of the polymeric device. In either of these embodiments, Batchelor specifies that the polymeric layer may include a bulk matrix containing a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent (see Batchelor Figs. 1 and 4 and page 2, paragraphs 18-21 and paragraph 24). It is inherent, or at least obvious to one having ordinary skill in the art, that in this embodiment of Batchelor the polymeric layer having the layer of biocatalysts or biomimetic catalysts on its surface would include a plurality of pores extending there through, otherwise the lipophilic salts or nitrite/nitrate or nitrosothiols would not be able to "continuously leak to the catalytic surface of the material" as specified by Batchelor (see Batchelor page 2, paragraphs 24-26).

16. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify layer 14 of Holleman to include any of the antithrombogenic embodiments taught by Batchelor, as discussed above, since such modifications to layer 14 of Holleman would provide an antithrombogenic implantable therapy and/or diagnostic lead which not only prevents fibrotic in-growth around each individual coil turn of electrode 10 but also prevents platelet activation and adhesion, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials. To clarify, it would have been prima facie obvious, for the reasons previously discussed, to either modify layer 14 of Holleman in view of Batchelor such that it comprises the double layer antithrombogenic material of Batchelor and/or it would have been prima facie obvious, for the reasons previously discussed, to modify layer 14 of Holleman in view of Batchelor such that it comprises only the catalytic agent material/portion and polymeric layer 12 of the lead provides the polymer material/portion, where in either modification, the polymer portion of the antithrombogenic double layer includes a bulk matrix containing a

reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent.

17. As to Claim 7, the Examiner applies an alternative interpretation of the Holleman reference where "the polymer layer" of Applicant's invention is considered to be synonymous with polymer elements 12 and 14 in combination. At column 2, lines 17-20, Holleman specifies that polymeric layers 14 and 12 "together form the lead body in the vicinity of electrode coil 10". Holleman expressly discloses that the electrode 10, coupled to a coiled conductor of the lead via sleeve 20, is partially imbedded in the outer surface of the combination polymeric layer 12, 14 in order to stabilize the electrode 10 with respect to the lead body formed by the combination polymeric layer 12, 14 and to prevent fibrous in-growth around the individual coil turns of the electrode 10. Furthermore, it is clear upon inspection of Holleman Fig. 1 that the outer surface of the combination polymeric layer 12, 14 is exposed between coil-turns of the electrode 10 (see Holleman Abstract, Fig. 1, column 3, lines 64-66 and column 4, lines 1-4). With this alternative interpretation of Holleman, the reference discloses the claimed invention except that it is not specified that the lead further comprise a layer of a catalytic agent, having nitrite reductase and/or nitrate reductase, or nitrosothiol reductase activity, present on the outer surface of the combination polymeric layer 12, 14 and being exposed between coil turns such that the catalytic agent converts nitrite/nitrate or nitrosothiols found in blood to nitric oxide.

18. Batchelor, however, teaches the use of biocompatible polymeric materials provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor

specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that by providing biocatalysts or biomimetic catalysts on blood contacting surfaces of implantable biomedical devices, platelet activation and/or adhesion onto these surfaces is prevented, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23).

19. Batchelor further teaches that a material in accordance with the antithrombogenic desirability may be made or manufactured in one of a plurality of embodiments. In one embodiment, a polymeric implantable medical device itself supplies the polymeric layer for the material and only a catalytic agent is attached to the surface of the polymeric device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to, at the location of electrode 10, modify the outer surface of combination polymeric layer 12, 14 Holleman in view of Batchelor such that a layer of a catalytic agent having nitrite reductase and/or nitrate reductase, or nitrosothiol reductase activity is present on the outer surface of the combination polymeric layer 12, 14 and exposed between the coil turns of electrode 10 due to the electrode 10 being slightly imbedded in that outer surface, as previously discussed, in order to provide an antithrombogenic implantable therapy and/or diagnostic lead which not only prevents fibrotic in-growth around each individual coil turn of electrode 10 but also prevents platelet activation and adhesion, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials.

20. As to Claims 8, 10-12 and 14, the Examiner again applies an alternative interpretation of Holleman in comparison to those interpretations previously presented. In particular, tubing 12 of Holleman is considered synonymous with Applicant's "elongate body" and tube 14 is considered synonymous with Applicant's "polymeric layer" overlaying the elongate body (see Holleman

Abstract and Fig. 1). Holleman specifies at column 2, lines 46-49 that the elongate body 12 may carry conductors that extend within elongate body 12 for coupling with distal pacing electrodes. In addition, Holleman expressly discloses that electrode 10 is coupled to an elongated coiled conductor and is overlaying and partially embedded in the outer surface of the polymeric layer 14 (see Holleman Abstract and Fig. 1.) With this alternative interpretation of Holleman, the reference discloses the claimed invention except that it is not specified that the lead further comprise a layer of a catalytic agent, having nitrite reductase and/or nitrate reductase, or nitrosothiol reductase activity, present on the outer surface of the polymeric layer 14 and being exposed between coil turns such that the catalytic agent converts nitrite/nitrate or nitrosothiols found in blood to nitric oxide.

21. Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that by providing biocatalysts or biomimetic catalysts on blood contacting surfaces of implantable biomedical devices, platelet activation and/or adhesion onto these surfaces is prevented, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23).

22. Batchelor further teaches that a material in accordance with the antithrombogenic desirability may be made or manufactured in one of a plurality of embodiments. In a first embodiment, the material includes a polymeric layer having a layer of a catalytic agent where the double layer

material is attached to the surface of a metal or polymeric implantable medical device. In a second embodiment, a polymeric implantable medical device itself supplies the polymeric layer for the material and only a catalytic agent is attached to the surface of the polymeric device. In either of these embodiments, Batchelor specifies that the polymeric layer may include a bulk matrix containing a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent (see Batchelor Figs. 1 and 4 and page 2, paragraphs 18-21 and paragraph 24). It is inherent, or at least obvious to one having ordinary skill in the art, that in this embodiment of Batchelor the polymeric layer having the layer of biocatalysts or biomimetic catalysts on its surface would include a plurality of pores extending there through, otherwise the lipophilic salts or nitrite/nitrate or nitrosothiols would not be able to "continuously leak to the catalytic surface of the material" as specified by Batchelor (see Batchelor page 2, paragraphs 24-26).

23. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify layer 14 of Holleman to include any of the antithrombogenic embodiments taught by Batchelor, as discussed above, since such modifications to layer 14 of Holleman would provide an antithrombogenic implantable therapy and/or diagnostic lead which not only prevents fibrotic in-growth around each individual coil turn of electrode 10 but also prevents platelet activation and adhesion, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials. To clarify, it would have been prima facie obvious, for the reasons previously discussed, to either modify layer 14 of Holleman such that it comprises the double layer antithrombogenic material of Batchelor and/or it would have been prima facie obvious, for the reasons previously discussed, to modify layer 14 of Holleman such that it comprises only the catalytic agent material/portion and polymeric layer 12 of the lead provides the polymer material/portion as taught by Batchelor where in either modification, the polymer portion of

the antithrombogenic double layer includes a bulk matrix containing a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent.

24. As to Claims 13 and 30, and as previously discussed, Batchelor teaches that an antithrombogenic material may include both a polymeric layer and a layer of a catalytic agent and further specifies that the double layer antithrombogenic material may be attached to implantable medical devices having metal-blood contacting surfaces (see Batchelor Fig. 4, page 2, paragraphs 18-25 and page 3, paragraph 46). It would have been obvious to one having ordinary skill in the art to modify the metal-blood contacting surfaces of the electrode 10 taught by Holleman with a coating of the double layer antithrombogenic material as taught by Batchelor, since such a modification prevent platelet activation and adhesion at the entire portion of the lead where the electrode 10 is disposed thereby lowering thrombus formation and other complications associated with interactions between this portion of the lead and the blood. The Examiner takes the position that such material, extending over the electrode 10 of the modified Holleman reference inherently allows electrical conduction through the material since the material may be applied as a film and may include a porous polymeric portion including polyetrafluorethylene (ePTFE) (see Batchelor page 2, paragraphs 18-22).

25. As to Claims 16-18, as previously discussed, Holleman specifies at column 4 that the lead may include the distal assembly of the body implantable lead taught by Stokes '680, incorporated by reference. The distal assembly of the lead taught by Stokes '680 includes a silicone rubber plug 38 held within the lead body 10 such that lipophilic salts leak from a reservoir of the plug 38, through the tip electrode 22, which is porous, and out the distal tip of the lead body 10 (see Stokes '680 Figs. 1-2 and column 3, lines 5-57).

26. ***Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holleman in view of Batchelor as applied to claims 1 and 4 above, and further in view of Shoberg et al. (U.S.***

5,584,873) (herein Shoberg). Similarly, Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holleman in view of Batchelor as applied to claims 1 and 8 above, and further in view of Shoberg. The previously modified Holleman reference discloses the claimed invention, as discussed above, except that elongate polymeric body 12 is not specified to be a multi-lumen tube. Shoberg, however, discloses a medical electrical lead including multiple conductors located within an elongated lead body 10. The lead body 10 is provided with multiple conductor lumens each containing a conductor and multiple compression lumens intermediate the conductor lumens. Shoberg teaches that such a multi-lumen lead body 10 provides for a substantial benefit in producing a lead with an ability to survive crushing forces and to avoid electrical short-circuit occurrence between the conductors of the lead in the event of fracture (see Shoberg Figs. 1 and 2, Abstract, column 1, lines 30-67 and column 2, lines 1-10). The lead of Shoberg includes an elongated defibrillation electrode 12, ring electrode 14 and tip electrode 16, each coupled to a conductor located within the lead body 10 (see Shoberg column 2, lines 42-51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the elongate body of Holleman in view of Batchelor in view of Shoberg such that the body is a multi-lumen tube in order to provide an improved lead resistant to crushing forces that occur during implantation and non-susceptible to electrical short-circuiting.

27. ***Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holleman in view of Batchelor as applied to claim 1 above, and further in view of Halperin et al. (U.S. 5,564,434) (herein Halperin).*** The previously modified Holleman reference discloses the claimed invention, as discussed above, except that the lead body formed by the polymeric layer 12 does not further comprise a physiological sensor capsule coupled to a conductor within the lead body. Halperin, however, teaches that it is well known in the art to employ a metal housed physiological sensor

module, read as a capsule 20 coupled to one or more extending conductors 14 and 16 in a medical lead in order to enable rate responsive pacing functions employing temperature or pressure sensing (see Halperin Abstract, Figs. 2 and 3 and column 7, lines 19-67). Since Holleman specifies that the disclosed lead may is applicable to "any elongated medical electrical lead empoloying any desired combination of additional electrodes, sensors, and connectors" (see Holleman column 4, lines 24-28) it have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead of Holleman in view of Batchelor and Halperin such that it comprises/includes a physiological sensor capsule coupled to a conductor extending within the elongate body of the lead formed by polymer layer 12 in order to allow rate responsive pacing/defibrillation utilizing parameters such as temperature and pressure and to provide the sensor capsule with improved biocompatibility.

28. ***Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holleman in view of Batchelor as applied to claim 22 above, and further in view of Fearnot et al. (U.S. 5,609,629) (herein Fearnot).*** The previously modified Holleman reference discloses the claimed invention as previously discussed except that it is not specified that the lead include a porous layer overlaying the layer of catalytic agent. Fearnot, however, teaches that it is well known in the art to overlay a nitric oxide promoting bioactive layer 18 of an implantable medical device 10 with a porous layer 20 such that the release of bioactive substance from layer 18 can be a very precise controlled release (see Fearnot Abstract, Fig. 1, column 3, lines 66-67, column 3, lines 1-29, column 5, lines 40-42, column 6, lines 24-30, column 7, lines 1-45, column 8, lines 55 and column 9, lines 28-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead of Holleman in view of Batchelor and Fearnot such that the lead includes a porous layer

overlaying the layer of catalytic agent in order to precisely control the rate nitric oxide is released into the blood stream from the catalytic agent.

29. ***Claims 24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes '680 in view of Batchelor.*** Stokes '680 expressly discloses an implantable therapy delivery and/or diagnostic lead comprising tines, read as fixation elements 26 capable of securing the lead to an implant site as known in the art (see, for example, Stokes '680 Abstract, Figs. 1-3 and column 2, lines 42-49). The lead may comprises an elongate coiled conductor 50, 76 extending within the lead and an insulating polymeric layer 24', 24" overlaying a portion of the lead in proximity to the implant site, the portion including an electrode 22', 22". Electrode 22' of the embodiment of Stokes '680 shown in Fig. 2 is coupled to elongate coiled conductor 50 and electrode 22" of the embodiment of Stokes '680 shown in Fig. 3 is coupled to elongate coiled conductor 76 (see Stokes '680 column 3, lines 34-43 and column 4, lines 9-19). Both electrode embodiments of Stokes '680 expressly disclose the use of sidewalls comprising a plurality of pores (i.e. path 32 and vent holes 36 in the Fig. 2 embodiment and path 54 and vent holes 66 in the Fig. 3 embodiment). Both embodiments of the lead additionally include a plug 38, 64 held within the porous sidewalls of the electrodes 22', 22". Plug 38, 64 is constructed of a polymer, such as silicone, and may be impregnated with a desired, water soluble drug. Surfaces of the polymeric plug 38, 64 of Stokes '680 make contact with body fluid via the plurality of pores 32, 36, 54, 66, as previously discussed. It is inherent that such body fluid includes blood when the lead of Stokes '680 is used transvenously placed within the heart to provide pacing to the heart. (see Stokes '680 Abstract, column 1, lines 15-68 and column 4, lines 20-49). Stokes '680 discloses the claimed invention, as previously discussed, except that it is not specified that the plug 38, 64 held within the porous sidewalls include a layer of a catalytic agent, having nitrite reductase and/or nitrate reductase, or nitrosothiol reductase activity present on the outer

surface of the plug 38, 64 such that the catalytic agent, exposed to blood through the plurality of pores 32, 36, 54, 66, converts nitrite/nitrate or nitrosothiols in the blood to nitric oxide.

30. Batchelor, however, teaches the use of polymeric biocompatible materials provided with biocatalysts/biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor further specifies that by providing biocatalysts or biomimetic catalysts "on blood contacting surfaces" of implantable biomedical devices, platelet activation and/or adhesion onto these surfaces is prevented, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23). Batchelor further teaches that a material in accordance with the antithrombogenic desirability may be made or manufactured in one of a plurality of embodiments. In one embodiment, a polymeric implantable medical device itself supplies the polymeric layer for the material and only a catalytic agent is attached to the surface of the polymeric device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer surface of plug 38, 64 taught by Stokes '680, such that plug 38, 64 includes a layer of a catalytic agent having nitrite reductase and/or nitrate reductase, or nitrosothiol reductase activity present on the outer surface of the plug 38, 64 such that the catalytic agent may converts nitrite/nitrate or nitrosothiols in the blood to nitric oxide as taught by Batchelor thereby providing a plug 38, 64 that prevents the formation of thrombus and platelet activation and/or adhesion at the location of the plurality of pores 32, 36, 54, 66 within the sidewalls of the electrodes 22', 22".

Response to Arguments

31. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Helland et al. (U.S. 4,033,357) (herein Helland) teaches that fibrosis is a response to thrombosis and therefore discloses a non-fibrosing implantable lead formed from non-thromogenic materials. Carson (U.S. 5,931,862) teaches that conductive ePTFE is often used to as a coating/covering on defibrillation electrodes to protect them from tissue in-growth. Krishnan (U.S. 7,013,182) discloses a sheath arranged to minimize or eliminate tissue in-growth while passing sufficient electrical energy to stimulate tissue.

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
January 21, 2008

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766
January 22, 2008